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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/785,169	02/23/2004	Mitchell Karl	43069-0003	8515

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EXAMINER	
SILVERMAN, ERIC E	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 11/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/785,169	KARL, MITCHELL	
	Examiner	Art Unit	
	Eric E. Silverman, PhD	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *03 October 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt of amendment and remarks and arguments enclosed therewith, filed 10/03/2005, is acknowledged.

After amendment, claims 1 – 13 are pending in this action.

Claim Objections

For reasons of record, the objections to claims 4, 7, and 10 are withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 – 13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection**.

Instant claims 1 and 3 now read, in part "a plurality of separate dispensers, each of the dispensers comprising a single day's dose of the at least first and at least second pharmacologically active agents".

The specification as filed does not support recited "plurality of separate dispensers". Accordingly, a person of ordinary skill in the art would doubt that the applicant was actually in possession of this aspect of the claimed invention as of the filing date of the application.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-12 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Pan et al., US Patent 5,190,970 in view of Endo et al., US Patent 5,569,464 and in further view of Steffen, US Patent 4,693,996. In addition, new Claim 13 is also rejected under 35 U.S.C. 103(a) as being unpatentable over Pan et al., US Patent 5,190,970 in view of Endo et al., US Patent 5,569,464 and in further view of Steffen, US Patent 4,693,996.

Pan teaches the use of two pharmaceutically active agents provided in combination (see abstract). Pan further teaches same when one of the active agents is an angiotensin converting enzyme inhibitor (see abstract) and when the two are mixed in a pharmaceutically acceptable liquid vehicle in appropriate amounts for oral administration (see column 12 lines 17-22).

Pan does not teach the inclusion of osmotic-adjusting agents or buffering agents in the composition, nor does Pan teach the composition where the second active agent is a diuretic, cardiac glycoside, beta blocker, nitrate, antiplatlet, vitamin, nutroceutical, or calcium channel blocker.

Endo teaches an aqueous pharmaceutical composition delivery form comprising the buffer sodium citrate, and vitamins (see column 3 lines 15-26 and column 4, line 41). Endo also teaches the inclusion of pharmaceutically acceptable salts of the hydroxy acids, which includes sodium chloride and potassium chloride (see column 5,

lines 16-18).

Steffen teaches aqueous pharmaceutical compositions for the treatment of heart-related ailments that may comprise agents other than the active agents (see, for example, column 3 lines 21-22 and column 4 lines 55 - 68). Stephens further teaches such compositions in an oral unit dosage form, wherein the dosage form is prepackaged (see column 5, lines 1-7). Stephen also teaches a method of making the composition by mixing the active agents and then adding the other agents in appropriate quantities (see column 4, lines 60-63).

Therefore, it would have been prime facie obvious to a person of ordinary skill in the art at the time of the invention to combine the angiotensin converting enzyme inhibitor containing composition of Pan with the vitamin composition of Endo with a reasonable expectation of success. The motivation for doing so is provided by Pan, who teaches that combining angiotensin converting enzyme inhibitor with other medicaments provides increased benefits. Such a composition would obviously include the excipients taught by Endo, in order to realize the full benefits of Endo's delivery form.

It would have been prime facie obvious to a person of ordinary skill in the art at the time of the invention to pre-package this composition according to the teachings of Steffen. Because Stephen describes a composition that is generally similar in nature to that which would result from the combination of Pan and Endo in that it is aqueous, liquid, and has one or more active agents and one or more non-active agents, a person of ordinary skill in the art would have a reasonable expectation of success in carrying

out such a manipulation.

It would also have been prime facie obvious to a person of ordinary skill in the art to make the compositions according to the method taught by Stephen. Because Stephen describes a composition that is generally similar in nature to that which would result from the combination of Pan and Endo in that it is aqueous, liquid, and has one or more active agents and one or more non-active agents, a person of ordinary skill in the art would have a reasonable expectation of success in carrying out such a manipulation.

With regard to limitations that the mixture be in a plurality of separate dispensers, each having a single day's medication, such is further obvious. Steffen teaches that the preparation is subdivided into unit dosages containing appropriate quantities of active components, in a prepackaged preparation (col. 5, lines 1 – 10). One of skill in the art would recognize that the "appropriate number" recited by Steffen, could be the appropriate number for a single day. The artisan would further recognize that the subdivisions may be connected or unconnected.

Furthermore, it would have been prime facie obvious to a person of ordinary skill in the art at the time of the invention to administer the composition for the treatment of a cardiac condition. Because the active agents in the obvious composition are known in the art to be useful for the treatment of cardiac conditions, it would be obvious to administer such a composition in order to treat a cardiac condition. It is obvious to prepare such a composition as an oral dosage form according to Stephen or Pan. An oral dosage form is designed for oral delivery. Thus, it would be further obvious to administer said oral dosage form composition orally, and a person of ordinary skill in the

art would have a reasonable expectation of success in doing so.

It would also be obvious to a person of ordinary skill in the art to make the dispensers close with a twist-off cap. A twist off cap is well known in the art as a mechanism for closing medication containers. For instance, a cap that can only be opened when a force is applied perpendicularly to the plane of twisting is well known as a type of child-proof cap, that cannot be opened easily by children. Accordingly, one of skill in the art would be motivated to use a twist-off cap to seal the medication dispenser in order to make the dispenser child-proof, and the artisan would have a reasonable expectation of success since such are well-known modifications to medication dispensers.

Response to Arguments

Applicant's arguments filed 10/03/2005 have been fully considered but they are not persuasive. Applicant argues only that the art of record does not teach or suggest the new limitation requiring separate dispensers, each having a day's worth of medication. This limitation is suggested by the art of record, as discussed above.

Claims 1 – 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pan et al., US Patent 5,190,970 in view of Endo et al., US Patent 5,569,464, Steffen, US Patent 4,693,996, as applied to claims 1 – 12 above, in further view of Bryant, US 3,308,962.

The teachings of Pan, Endo, and Steffen are discussed above.

Bryant teaches a medicine packaging, organization and dispensing system comprising separate containers, each of which contains a day's worth of medication (see figures 1 – 12 and descriptions thereof).

Accordingly, it would be prime facie obvious to a person of ordinary skill in the art at the time of the invention to use the system of Byrant in packaging, organizing and distributing the medications Pan, Endo and Steffan. The motivation to do so comes from Byrant, who teaches that this system and method are flexible, and can be used with solid and liquid medications, or a combination thereof (col. 6, lines 35 – 53). Accordingly, the artisan would expect a product and method of administrating medications according to Pan and Endo and Steffan, wherein the pre-packaging was in separate containers each with a daily dosage of the medications according to Bryant. Since these methods are common practice in the art, the artisan would have a reasonable expectation of success.

It would also be obvious to a person of ordinary skill in the art to make the dispensers close with a twist-off cap. A twist off cap is well known in the art as a mechanism for closing medication containers. For instance, a cap that can only be opened when a force is applied perpendicularly to the plane of twisting is well known as a type of child-proof cap, that cannot be opened easily by children. Accordingly, one of skill in the art would be motivated to use a twist-off cap to seal the medication dispenser in order to make the dispenser child-proof, and the artisan would have a reasonable expectation of success since such are well-known modifications to medication dispensers.

Conclusion

No claims are allowed. No claims are free of the prior art.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric E. Silverman, PhD whose telephone number is 571 272 5549. The examiner can normally be reached on Monday to Friday 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571 272 0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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